



CALIFORNIA  
HEALTHCARE  
ASSOCIATION

*Providing Leadership in  
Health Policy and Advocacy*

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Documents Branch  
Food & Drug Administration  
5630 Fishers Lane, #1061  
Rockville, MD 20852

To Whom It May Concern:

The California Healthcare Association represents nearly 500 hospitals. On behalf of those member hospitals, I am writing to you regarding a draft guidance document (HFA-305) that proposes health providers initiate an HCV Lookback Program using the 1990 HCV test. The draft document also proposes providers "search historical records dating back indefinitely to the extent that electronics or other readily retrievable records exist."

Less than 5% of hospitals with hepatitis C patients are infected by transfusion. Requiring an indefinite Lookback will use valuable resources with little or no positive results. We also understand there is a high percentage of false-positive. This would unduly alarm many people, most of them senior citizens.

We believe you will agree with our member hospitals that all Lookback proposals need to be evaluated weighing the benefits to the patient. This one doesn't seem to pass the test. We do not believe the 1990 Lookback is justified.

May we suggest the FDA consider patients that visit a hospital or physician's office revealing a blood transfusion in their past be tested for Hepatitis C? Instead of the shotgun approach being proposed this would at least provide a target population.

We strongly encourage a re-consideration of the proposed indefinite Lookback.

Sincerely,

Dorel Harms  
Vice President, Quality and Professional Services

DFH:co

cc: Robin Biswas, MD  
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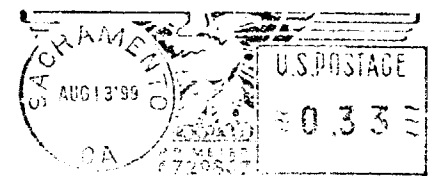
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